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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,188	09/21/2000	Scott E. Andersen	38-21(51464)B	8378

7590 08/13/2002

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EXAMINER
GUNTER, DAVID R

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/667,188	Applicant(s) ANDERSEN ET AL.	
	Examiner BJ Forman	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *3-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Traversal

The examiner acknowledges the applicant's election with traverse of Group I (Claims 1 and 2) in paper number 8, received May 31, 2002. The applicant asserts that there are two grounds for traversal: (1) that the nucleic acid of Group I, protein of Group II, and transgenic plant of Group III can be searched simultaneously without creating an undue burden on the examiner; and (2) that the restriction to a single nucleotide sequence is contrary to MPEP Section 803.04 which states that ten sequences constitute a reasonable number for examination purposes.

These arguments are not found persuasive. In regard to the first argument, the basis for restriction of the nucleotide, protein, and transgenic plant is based on the fact that a polynucleotide of Group I, the polypeptide of Group II, and the transgenic plant of Group III represent three substantially different inventions. A polynucleotide is a substantially different molecule than the polypeptide it encodes due to differences in the structure, function, properties, and potential applications of each molecule. Because the polypeptide and polynucleotide are unrelated in terms of their structure, function, properties, and potential applications, they require separate searches.

Although a transgenic plant (Group III) will, by definition, include a polynucleotide of Group I, the production of a transgenic plant represents only one of many potential uses for a polynucleotide. Other uses include northern blotting, Southern blotting, acting as a template for PCR amplification, or the identification of DNA binding proteins. Because the polynucleotide

and the transgenic plant are related as a product and process of use, and because the product can be used in a plurality of materially different processes, a restriction requirement is deemed proper. A database search for a polynucleotide sequence would not necessarily reveal the existence of a transgenic plant comprising this sequence. A separate literature search for the transgenic plant would be required.

A transgenic plant of Group III comprising a polynucleotide of Group I will produce a polypeptide of Group II. However, production by a transgenic plant represents only one of many potential methods by which the polypeptide can be produced. Other methods include solid-state synthesis, purification of the recombinant protein from transgenic bacteria, or isolation of the protein from a natural source. Because the polypeptide is related to the plant as a product and process of making, and because the peptide can be made by a plurality of different processes, a restriction requirement is deemed proper. A database search for a polypeptide sequence would not necessarily reveal the existence of a transgenic plant expressing the polypeptide. A separate literature search for the transgenic plant would be required.

In regard to the applicant's assertion that MPEP Section 803.04 entitles the applicant to elect ten nucleotide sequences, Section 803.04 states that "in most cases, up to ten independent and distinct nucleotide sequences will be examined." [emphasis added] Section 803.04 further states that "applicants may petition pursuant to 37 CRF 1.181 for examination of additional nucleotide sequences by providing evidence that the different nucleotide sequences do not cover independent and distinct inventions." In the absence of such evidence each nucleotide sequence is presumed to represent an independent and distinct invention.

The restriction requirement is still deemed proper, and is therefore made FINAL.

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (page 38, lines 4-6), determining whether a plant contains a mutation (page 38, lines 19-20), and acting as molecular tags to isolate genetic regions, isolate genes, map genes, and determine gene function (page 15, lines 20-24). These are non-specific uses that are applicable to polynucleotides in general and not particular or specific to the polynucleotide claimed

Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and

substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

2. Claims 1 and 2 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

3. **No claims are allowed.** However, the examiner notes that the claims are free of the prior art. The closest match found on a search of DNA databases was Genbank accession number BE428765, established July 26, 2000, a 93.1% match to SEQ ID NO: 1 of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, PhD
August 1, 2002